Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429)

bovine genital campylobacteriosis

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Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): bovine genital campylobacteriosis

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Abstract

Bovine genital campylobacteriosis has been assessed according to the criteria of the Animal Health Law (AHL), in particular criteria of Article 7 on disease profile and impacts, Article 5 on the eligibility of bovine genital campylobacteriosis to be listed, Article 9 for the categorisation of bovine genital campylobacteriosis according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to bovine genital campylobacteriosis. The assessment has been performed following a methodology composed of information collection and compilation, expert judgement on each criterion at individual and, if no consensus was reached before, also at collective level. The output is composed of the categorical answer, and for the questions where no consensus was reached, the different supporting views are reported. Details on the methodology used for this assessment are explained in a separate opinion. According to the assessment performed, bovine genital campylobacteriosis can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL. The disease would comply with the criteria as in sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1). The assessment here performed on compliance with the criteria as in section 3 of Annex IV referred to in point (c) of Article 9(1) is inconclusive. The animal species to be listed for bovine genital campylobacteriosis according to Article 8(3) criteria is mainly cattle as susceptible and reservoir.

Keywords: Bovine genital campylobacteriosis, BGC, bovine venereal campylobacteriosis, BVC, *Campylobacter fetus* subsp. *venerealis*, Animal Health Law, listing, categorisation, impact

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

The background and Terms of Reference (ToR) as provided by the European Commission for the present document are reported in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9 and 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017).

1.2. Interpretation of the Terms of Reference

The interpretation of the ToR is as in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9 and 8 within the AHL framework (EFSA AHAW Panel, 2017).

The present document reports the results of assessment on bovine genital campylobacteriosis (BGC) according to the criteria of the AHL articles as follows:

- Article 7: bovine genital campylobacteriosis profile and impacts
- Article 5: eligibility of bovine genital campylobacteriosis to be listed
- Article 9: categorisation of bovine genital campylobacteriosis according to disease prevention and control rules as in Annex IV
- Article 8: list of animal species related to bovine genital campylobacteriosis.

2. Data and methodologies

The methodology applied in this opinion is described in detail in a dedicated document about the ad hoc method developed for assessing any animal disease for the listing and categorisation of diseases within the AHL framework (EFSA AHAW Panel, 2017).

3. Assessment

3.1. Assessment according to Article 7 criteria

This section presents the assessment of BGC according to the Article 7 criteria of the AHL and related parameters (see Table 2 of the opinion on methodology (EFSA AHAW Panel, 2017)), based on the information contained in the fact-sheet as drafted by the selected disease scientist (see Section 2.1 of the scientific opinion on the ad hoc methodology) and amended by the AHAW Panel.

3.1.1. Article 7(a) Disease Profile

Campylobacter fetus subsp. *venerealis* (Cfv) is described as the causative agent of BGC. BGC is a venereal disease, also known as bovine venereal campylobacteriosis (BVC). BGC is sexually transmitted and characterised by infertility, early embryonic death and abortions in bovines (Thompson and Blaser, 2000).

BGC is listed by the World Organization for Animal Health (OIE) since it is deemed to have socioeconomic and public health implications. Several countries have been successful in eradicating BGC, whereas in many countries BGC is still endemic. The incidence of BGC is highest in low- and middle-income countries (LMIC) where natural breeding of cattle is widely practiced, compared to high income countries where cattle are bred through artificial insemination (AI) (Mshelia et al., 2010).

Compared to several other agents causing disease in animals, detailed data on pathogenesis, epidemiology and transmission are lacking due to the fact that there are no reliable serological assays and detection of the causative agent is difficult. It requires specific laboratory equipment to cultivate the agent under microaerobic conditions, very well-trained technical staff to recognise the bacterial growth among more rapid growing contaminating microflora (expertise) and once a suspected isolate has been cultivated, easy-to-perform reliable identification methods are lacking. There are hardly monitoring programs implemented showing numerator and denominator and data are often available from necropsy room findings in aborted fetuses (mostly lacking a denominator to estimate the prevalence). These findings are even more complicated by the fact that in several studies only identification at species level is reported (with an undefined fraction Cfv, the causative agent of BGC)

and in some studies the isolates are identified at subspecies level. Finally, in particular in older literature the reliability of the subspecies identification is questionable due to the lack of molecular techniques. The worldwide database on the presence of a disease (OIE) shows positive findings but also their prevalence data are lacking. This results into scarce data on basic aspects of BGC.

3.1.1.1. Article 7(a)(i) Animal species concerned by the disease

Susceptible animal species

Parameter 1 – Naturally susceptible wildlife species (or family/orders)

The naturally susceptible wildlife species of Cfv causing BGC is cattle (*Bos taurus*) (OIE, 2012).

Parameter 2 – Naturally susceptible domestic species (or family/orders)

The naturally susceptible wildlife species of Cfv causing BGC is cattle (*B. taurus*) (OIE, 2012).

Parameter 3 - Experimentally susceptible wildlife species (or family/orders)

No experimentally susceptible wildlife species for Cfv causing BGC have been described. It is to be expected that wildlife cattle (*B. taurus*) is the only wildlife species that is susceptible for BGC.

Parameter 4 – Experimentally susceptible domestic species (or family/orders)

Experimentally susceptible domestic species for Cfv causing BGC are cattle (*B. taurus*) (Corbeil et al., 1975; Cipolla et al., 1994) and guinea pigs (*Cavia porcellus*) (Plummer, 2017).

Reservoir animal species

Parameter 5 – Wild reservoir species (or family/orders)

The wild reservoir species for Cfv causing BGC is cattle (*B. taurus*).

Parameter 6 – Domestic reservoir species (or family/orders)

The domestic reservoir species for Cfv causing BGC is cattle (*B. taurus*) (Blaser et al., 2008).

3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations

Morbidity

Parameter 1 – Prevalence/incidence

Although BGC is wide-spread in the world, the lack of monitoring programmes for this disease in many countries makes, it difficult to estimate the prevalence rates of BGC world-wide. As shown in Table 1, the estimates are based on small studies with highly questionable representability. The prevalence of herds infected with Cfv causing BGC is relatively high in LMIC compared to low prevalence or even eradication of BGC in developed countries (data available of the OIE and published data (Mshelia et al., 2007, 2010)).

Table 1: *C. fetus* prevalence world-wide

Country	Samples	Result	Reference
Argentina	Aborted bovine fetuses	26 of 354 tested fetuses (7%) were *C. fetus* positive	Campero et al. (2003)
Australia	Aborted bovine fetuses	11% of 265 tested fetuses were *C. fetus* positive	Jerrett et al. (1984)
Brazil	Preputial washings of bulls	170 of 327 tested bulls (52.3%) and 17 of 19 tested farms (89.5%) were *C. fetus* positive	Pellegrin et al. (2002)
Brazil (Goiás)	Vaginal mucus samples of cows	22.4% of 1,685 cows were *C. fetus* positive	Andrade et al. (1986)
USA (California)	Blood samples of cows	189 of 400 (47%) tested cows were *C. fetus* positive	Akhtar et al. (1990)
USA (California)	Blood samples of dairy cows	22.2% of 790 tested cows were *C. fetus* positive	Akhtar et al. (1990)

Country	Samples	Result	Reference
Canada	Preputial washings of bulls	18 of 529 (3%) bulls tested were *C. fetus* positive	Devenish et al. (2005)
Colombia	Preputial washings of bulls	103 farms tested, 15% of the farms had *C. fetus* positive bulls	Griffiths et al. (1984)
Egypt		BGC prevalence of 10% in buffalo cows	Mshelia et al. (2010)
India (Calcutta)	Fecal samples from cattle	No *C. fetus* found in 120 samples	Chattopadhay et al. (2001)
India (West Bengal)		Estimated BGC prevalence of 6% in cattle	Mshelia et al. (2010)
Japan	Fecal samples from cattle	26.5% of 94 tested samples were Cff positive. 'A few' samples were Cfv positive	Giacoboni et al. (1993)
Japan	Fecal samples from healthy cattle	13 of 338 (4%) samples were *C. fetus* positive	Ishihara et al. (2004)
New Zealand	Vaginal mucus samples from cows and preputial washings from bulls	1.230 mucus samples from 125 beef cow herds were tested, 70% of herds had > 1 *C. fetus* positive CVM sample All 54 preputial washings from 9 herds were *C. fetus* negative	McFadden et al. (2005)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	15 of 585 (3%) tested bulls were *C. fetus* positive 5 of 104 (5%) tested cows were *C. fetus* positive	Bawa et al. (1991)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	3.7% of vaginal mucus samples of cows were *C. fetus* positive 11% of preputial washings of bulls were *C. fetus* positive	Mshelia et al. (2010)
Nigeria	Vaginal mucus samples from cows and preputial washings from bulls	Total; 270 bovine samples tested, consisting of 170 preputial washings from bulls and 100 vaginal mucus samples of cows. Of these 270 samples, 2.2% were Cfv positive and 1.5% were Cff positive	Mshelia et al. (2012)
North America	Fecal samples from dairy cows cattle	5% of 720 cows were *Campylobacter* spp. positive	Harvey et al. (2004)
Malawi	Vaginal mucus samples from cows and preputial washings from bulls	1 bull was tested positive for vibriosis Vaginal mucus samples gave no clear result	Klastrup and Halliwell (1977)
Scotland	Preputial washings of bulls	0% of 109 tested bulls were *C. fetus* positive	McGowan and Murray (1999)
South Africa (Republic of Transkei)	Preputial washings of bulls	10 of 14 (71%) tested sites were *C. fetus* positive	Pefanis et al. (1988)
South Africa (Gauteng province)	Preputial washings of bulls	2.1% of 143 tested bulls were *C. fetus* positive	Njiro et al. (2011)
Tanzania	Preputial washings of bulls	3 of 58 (5.1%) tested bulls were Cfv positive	Swai et al. (2005)
Turkey	Preputial washings of bulls and aborted bovine fetuses	Cfv is isolated from both bulls and aborted fetuses	Mshelia et al. (2010)
United Kingdom	Aborted bovine fetuses	28 of 161 (17%) tested samples were *C. fetus* positive	Devenish et al. (2005)
Zimbabwe	Aborted bovine fetuses	9.5% of 21 tested fetuses were *C. fetus* positive Estimated; BGC prevalence is 33% in cows in Zimbabwe	Mshelia et al. (2010)

Cff: *Campylobacter fetus* subsp. *fetus*; Cfv: *Campylobacter fetus* subsp. *venerealis*.

Parameter 2 – Case-morbidity rate (% clinically diseased animals out of infected ones)

Bulls are asymptomatic carriers of Cfv, so by definition the case-morbidity rate is 0% in these. The case-morbidity rate in cows is unknown, since infection in naturally served animals is mainly detected through the BGC disease symptoms, such as abortion as most clear symptom, and there are no data of the total population of infected animals.

Mortality

Parameter 3 – Case-fatality rate

Infection with Cfv will not cause death of the infected bull and/or cow, but can result in embryo mortality and abortion. The disease can spread rapidly through a herd and abortions and/or infertility due to BGC can reduce the annual weaning rate by 10% (Mshelia et al., 2007).

3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease

Cfv is restricted to the genital tract of cattle and no human cases are reported, except for one isolate from a woman with bacterial vaginosis in Sweden in 1987 (Holst et al., 1987).

3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

Parameter 1 – Resistant strain to any treatment even at laboratory level

All *C. fetus* strains and most Cfv strains are resistant to naladixic acid and all *C. fetus* strains are sensitive to cephalothin (On, 1996). In a field study, 1,084 *C. fetus* strains were isolated from bovines in Alberta and 95% of the isolates showed to be resistant to naladixic acid, 60% of the isolates was resistant for doxycycline, 57% was resistant to tetracycline and 1% was resistant to ciprofloxacin and enrofloxacin (Inglis et al., 2006). The subspecies, however, was not reported and given that the isolates were obtained from faeces, it might be *C. fetus* subsp. *fetus* only. There is one study from Germany specifically reporting on susceptibility (Hanel et al., 2011). They report full susceptibility of 50 investigated strains to gentamicin. In 14% of the strains, there was reduced susceptibility to one or more antimicrobials, mostly to lincomycin and spectinomycin.

3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment

Animal population

Parameter 1 – Duration of infectious period in animals

BGC infections in cows are usually self-limiting and most cows usually regain fertility within 5 months following elimination of the infection from the uterus (Timoney et al., 1988). However, in an experimental study, the infection persisted in cows for several months, possibly more than a year (Cipolla et al., 1994). Bulls can be life-long carriers of the pathogen (Blaser et al., 2008).

Parameter 2 – Presence and duration of latent infection period

For bulls, the latent infection period of Cfv causing BGC is from the moment of infection as they can act as a vector to transmit the agent to the next animal. For cows, this period is unknown.

Parameter 3 – Presence and duration of the pathogen in healthy carriers

It has been estimated that up to 10% of infected animals remain life-long carriers of Cfv causing BGC (Irons et al., 2004), whereas cows can become permanent vaginal carriers (Dekeyser, 1984) and older bulls can be life-long carriers in the crypts of the prepuce (García et al., 1983).

Environment

Parameter 4 – Length of survival (dpi) of the agent and/or detection of DNA in selected matrices (soil, water, air) from the environment (scenarios: high and low T)

Soil and water in cattle fields can be contaminated with *C. fetus*, however data about the length of survival of *C. fetus* in the environment is lacking. *Campylobacter coli* and *Campylobacter jejuni* can survive up to 10 months in cattle manure; however, the survival of these *Campylobacter* spp. is apparently quite different from *C. fetus* and this must be extrapolated with care (Wagenaar et al., 2014).

3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans

Routes of transmission

Parameter 1 – Types of routes of transmission from animal to animal (horizontal, vertical)

The route of transmission from animal to animal of Cfv is venereal with mainly asymptomatic bulls spreading the infection. Cows become infected through natural service or AI with contaminated semen. Bulls can become infected by serving an infected cow and transmission may occur between bulls during mounting. Vertical transmission has never been reported.

Parameter 2 – Types of routes of transmission between animals and humans (direct, indirect, including food-borne)

Not applicable – humans are not susceptible to Cfv.

Speed of transmission

Parameter 3 – Incidence between animals and, when relevant, between animals and humans

The transmission of Cfv between animals within a herd depends on the presence of a 'vector'; an infected bull that spreads the infection between animals, because BGC is a venereally transmitted infection. However, no quantitative estimates are available in bibliography.

Parameter 4 – Transmission rate (beta) (from R_0 and infectious period) between animals and, when relevant, between animals and humans

No data available about the transmission rate of BGC between animals.

3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, where the disease is not present in the Union, the risk of its introduction into the Union

Presence and distribution

Parameter 1 – Map where the disease is present in the EU

The map where BGC is present in the European Union (EU) is depending on the self-reporting of the country and this will certainly not show a full picture. The BGC distribution in the EU in 2016 as reported to OIE is presented in Figure 1.

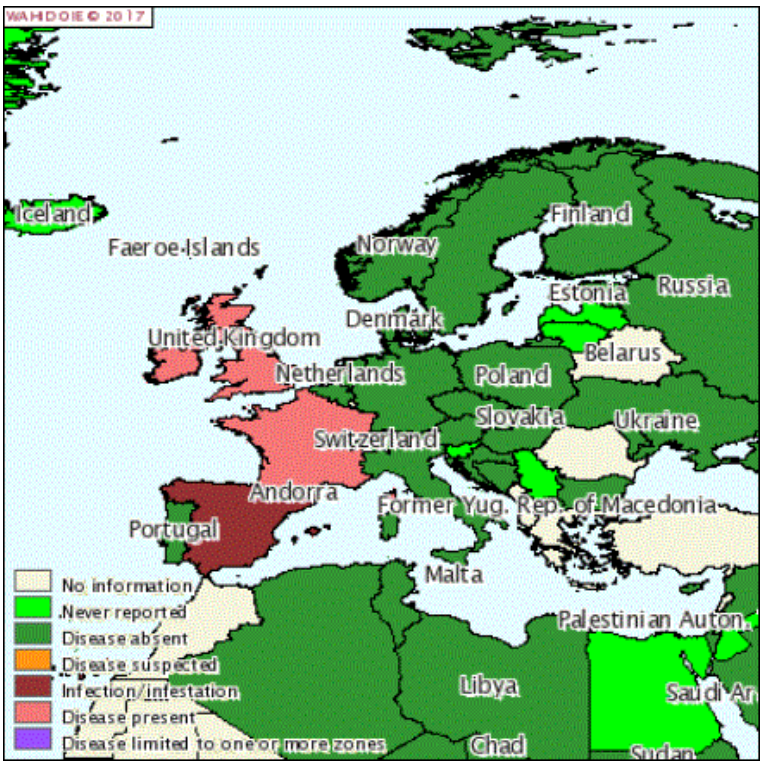

Figure 1: BGC distribution in the EU in 2016 (obtained from OIE (online))

Parameter 2 – Type of epidemiological occurrence (sporadic, epidemic, endemic) at MS level

The use of AI with BGC-free semen in Europe has greatly reduced the incidence of BGC. In countries from which BGC is reported, the type of epidemiological occurrence is only sporadic cases. For the sporadic cases, there are no studies on risk factors. Furthermore, the notification of BGC cases in Europe to OIE may be affected by underreporting (OIE, online).

Risk of introduction

Parameter 3 – Routes of possible introduction

As some countries report on a more regular basis cases (e.g. the UK), the pathogen is frequently detected in some European countries but the disease is sporadic (few outbreaks). In countries that do not report cases and are supposed to be free of BGC, there is a risk for introduction of BGC. The routes of possible introduction of BGC are import of infected cattle or contaminated bovine products, like semen and embryos.

Parameter 4 – Number of animal moving and/or shipment size

In 2014, the EU has imported around 9.7 million doses of bovine semen (Eurostat; The European Platform of Exporters of Bovine Genetics (ExPla)).

Parameter 5 – Duration of infectious period in animal and/or commodity

The duration of the infectious period in animals is mentioned in Section 3.1.1.5 of this fact-sheet.

Parameter 6 – List of control measures at border (testing, quarantine, etc.)

The general animal health requirements governing the intra-EU trade and import of bovine semen are laid down in Council Directive 88/407/EEC[1] and for bovine embryos in Council Directive 89/556/EEC.[2] These directives harmonise the animal health conditions for the trade within the EU and import to the EU from third countries, as well as the conditions of collection and storage. According to Council Directive 88/407/EEC, bulls whose semen is used for intra-community trade must be kept in quarantine before being admitted to an AI station. During the quarantine, bulls younger than 6 months are tested once for BGC and bulls older than 6 months are tested three times with 1 week intervals. Bulls that are in production must be tested annually. Bulls that are on hold are excluded with the proviso that when they are longer than 6 months on hold, they should be tested at the earliest 30 days prior to the resumption of the semen production. Bulls in non-EU countries are mainly tested twice per year.

Bulls are screened for BGC as described in the Terrestrial Animal Health Code by the OIE (2013).

If an animal is tested positive for BGC in an AI station, the AI station is closed and all semen obtained in the period from the latest negative test will be destroyed, according to Council Directive 88/407/EEC. All bulls will be treated with antibiotics and must be tested negative for BGC for 3 times with 2 weeks interval, before the AI centre is allowed to continue their production.

Parameter 7 – Presence and duration of latent infection and/or carrier status

The presence and duration of the latent infection and/or carrier status of BGC are mentioned in Section 3.1.1.5 of this fact-sheet.

Parameter 8 – Risk of introduction

If animals are infected or products are contaminated, the risk of introduction of BGC to the EU is high, but spread can be prevented by the control measures of AI centres and treatment of animals.

3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools

Diagnostic tools

Parameter 1 – Existence of diagnostic tools

BGC is diagnosed by diagnostic tools prescribed by the OIE (2012). The immunofluorescence antibody test (IFAT) is suitable to detect if a sample contains suspected *C. fetus* bacteria, but for definite diagnosis confirmation has to be done by isolating *C. fetus* from the sample. The isolation of the pathogen causing BGC can be challenging, since *C. fetus* is slow-growing and requires specific microaerobic conditions. It is critical that collected samples are sent immediately to the laboratory and cultured. If transport takes long, transport medium should be used. It is recommended to use selective Skirrow medium to isolate *C. fetus*. Alternatively, the filtration-technique can be used, where the sample is brought onto a 0.65 μm filter, allowing the *Campylobacter* bacteria to pass to a non-selective blood-based (5–7% blood) medium. Identification of *C. fetus* can be done with biochemical tests or molecular tests, as described in the OIE manual (OIE, 2012). Serological assays are not suitable for diagnosis due to cross-reaction between *C. fetus* subsp. *fetus* and *C. fetus* subsp. *venerealis*.

Control tools

Parameter 2 – Existence of control tools

BGC can be controlled by vaccination (Section 3.1.4.2), antimicrobials (Section 3.1.4.3), the separation of infected from non-infected animals and control measurements for the prevention of introduction to a herd by infected animals or their products (Section 3.1.1.7 Parameter 6), including quarantine measurements. Artificial insemination is considered to be the most effective for controlling BGC, as is evidenced by farms that have changed from natural breeding to controlled AI programmes (Figueiredo et al., 2002).

[1] Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra- Community trade in and imports of deep-frozen semen of domestic animals of the bovine species. OJ L 194, 22.7.1988, p. 10–23.

[2] Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species. OJ L 302, 19.10.1989, p. 1–11.

3.1.2. Article 7(b) The impact of diseases

3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy

The level of presence of the disease in the Union

Parameter 1 – Number of MSs where the disease is present

See Section 3.1.1.7, BGC is sporadic in several MSs. In 2016, sporadic cases of BGC were reported in four MSs: the United Kingdom, Ireland, France and Spain. The presence of the disease in EU countries from 2005 to 2016 is presented in Table A.1 in Appendix A.

The loss of production due to the disease

Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation

Control measures prevent the spread of BGC within the EU. Data about production losses in the EU are not available; however, it was estimated that during the first year of infection, the gross profit margins may be reduced by 66% and when the disease becomes established within a herd, gross profit margins are 36% lower than those of uninfected herds (Hum et al., 1994).

In Argentina, weaning rates in BGC-infected herds decrease by 10%, which accounts for an annual loss of $165 million (Jimenez et al., 2011).

In the modern dairy industry, it appears that more than 90% of dairy calves are born to AI. For example, in Denmark in 2015, around 17% of first parity dairy cows and 7% of older dairy cows were bred using natural service, with the balance using AI and overall for dairy cattle, 90% are inseminated using AI (SEGES, 2016). Similarly in France, 79% of births in dairy herds are by AI (IDELE, 2017). In Ireland, extrapolated data from the Irish Cattle Breeding Federation indicate approximately 45–60% of calves from the dairy herds are sired by AI (ICBF, 2017). According to the German Cattle Breeders' Federation, in Germany around 25% of cattle farms use AI (ADR, 2016), most probably those are almost all farms keeping dairy cows. In the Netherlands, in 2016 approximately 225,000 natural matings were registered as compared to 1.6 million first AI. In Finland, dairy herds are bred using AI even if in some larger herds also natural mating is used.

Therefore, the economic losses due to BCG in the EU are mostly linked to the beef cattle sector where natural mating is used. Most of the meat bovine herd in Europe is located in four EU Member States: France (34.4%), Spain (15.2%), the United Kingdom (12.8%) and Ireland (8.7%). Together, they host more than 70% of the European meat herd (EUROSTAT, online). In France, only 13% of beef cattle are bred from AI (IDELE, 2017). In the UK, the majority of beef herds use natural service. AI in beef cows is still uncommon in the UK due to the problems of heat detection and handling for AI (Penny, 2017). In Ireland, only about 23% of calves in beef herds are bred by AI (Agriland, online) and around 80,000 beef stock bulls were present during 2016 (ICBF, 2017). In Italy, data from the National Data Bank on farm animals indicate 17% 'linea vacca-vitello' beef cows representing 900,000 animals are bred by natural service (BDN, online). In Spain, around 95% of beef cattle use natural services (UGAVAN, 2017).

3.1.2.2. Article 7(b)(ii) The impact of the disease on human health

Not applicable – humans are not susceptible to infection with BGC.

3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare

Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

Infection of BGC in bulls is asymptomatic. Infection in cows can result in moderate endometritis and salpingitis and cows can become infertile for several months, but usually not life-long. Since infection is often not detected for a long time or only when fertility rates drop, clinical symptoms seem to be very weak, if any, suggesting a rather minor impact on animal welfare.

3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment

Biodiversity

Parameter 1 – Endangered wild species affected: listed species as in CITES and/or IUCN list

Only cattle (*B. taurus*) are reported to be infected with BGC; however, it cannot be excluded that rare bovine species on the CITES and/or IUCN list can also be infected with BGC; studies are, however, not available.

Parameter 2 – Mortality in wild species

BGC can cause embryonic death in wild bovines.

Environment

Parameter 3 – Capacity of the pathogen to persist in the environment and cause mortality in wildlife

Soil and water can be contaminated with *C. fetus*, however data about the length of survival of *C. fetus* in the environment is lacking.

3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism

Parameter 1 – Listed in OIE/CFSPH classification of pathogens

BGC is an OIE-listed disease but not listed by the CFSPH.

Parameter 2 – Listed in the Encyclopaedia of Bioterrorism Defence of Australia Group

BGC is not listed in the Encyclopaedia of Bioterrorism Defence of Australia Group.

Parameter 3 – Included in any other list of potential bio- agro-terrorism agents

BGC is not included in any other list of potential bio- agro-terrorism agents.

3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures

3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities

Availability

Parameter 1 – Officially/internationally recognised diagnostic tool, OIE certified

Diagnostic tests for BGC are prescribed by the OIE (2012) and include immunofluorescence and an antigen-enzyme-linked immunosorbent assay (ELISA) assay to detect *C. fetus* as well as isolation and identification methods of the agent.

Effectiveness

Parameter 2 – Se and Sp of diagnostic test

IFAT to detect *C. fetus* subsp. *venerealis* has a reported sensitivity and specificity of 92.6% and 88.9% and the detection limit ranges between 102 and 104 CFU/mL (Figueiredo et al., 2002). The OIE recommended tests to diagnose BGC are the detection of the antigen (bacterium) by culture or the combination of an antigen catching ELISA to detect the presence of *C. fetus* species cultured in transport medium followed by isolation. This ELISA has a specificity of up to 98.5% (Brooks et al., 2004; Devenish et al., 2005). The sensitivity of the culturing method is not determined but the number of *C. fetus* in preputial samples of infected bulls range from < 102 to $> 2 \times 105$ organisms per millilitre (Clark, 1971), which can be below the detection limit of the recommended methods. Once the bacterium has been isolated, subspecies identification is very challenging and no molecular diagnostic test is available with 100% sensitivity and 100% specificity to identify *C. fetus* subsp. *venerealis* (OIE, 2012; van der Graaf-van Bloois et al., 2013). Whole genome sequencing can be used to identify *C. fetus* subspecies with 100% specificity. Alternatively, an ELISA can be used to detect antibodies. This technique, however, is not recommended for individual cases and this assay lacks the specificity in differentiating the two subspecies and can therefore not be used to diagnose BGC.

Feasibility

Parameter 3 – Type of sample matrix to be tested (blood, tissue, etc.)

In bulls, smegma samples may be obtained by scraping, suction or by preputial washing (OIE, 2012). The amount of *C. fetus* bacteria recovered from scraping samples will be greater than with the suction or preputial washing methods. Furthermore, less contamination from background microflora was observed in scraping samples compared with the samples collected using the other two methods (Tedesco et al., 1977).

Cows or heifers should be sampled when the animals are close to oestrus or are in oestrus. Cervico-vaginal mucus samples may be obtained by swabbing, suction, or by washing the vaginal cavity (OIE, 2012).

Aborted bovine fetuses, including the placenta, can be tested to detect an infection with *C. fetus*. The stomach contents (abomasal fluid), lungs and liver have been shown to be the best samples for the recovery of the bacterium (OIE, 2012).

3.1.4.2. Article 7(d)(ii) Vaccination

Availability

Parameter 1 – Types of vaccines available on the market (live, inactivated, DIVA, etc.)

Several commercial vaccines are available for BGC consisting of inactivated *C. fetus* cells, including Vibrin® (Pfizer), Vibrio Leptoferm 5 (Pfizer) and BioAbortogen H (San Jorge Bago, Argentina). Both male and female cattle can be vaccinated against *C. fetus*.

Parameter 2 – Availability/production capacity (per year)

Unknown.

Effectiveness

Parameter 3 – Field protection as reduced morbidity (as reduced susceptibility to infection and/or to disease)

According to information of the producer, the use of Vibrin can increase pregnancy rates in vaccinated heifers up to 44% compared to non-vaccinated control heifers. Both male and female cattle can be vaccinated against *C. fetus*. Vaccination of bulls might help to control the spread of infection but the effect is limited.

Parameter 4 – Duration of protection

It is recommended to vaccinate against BGC by annual revaccination with a single dose between 30 days and 7 months before breeding (Pfizer, online).

Feasibility

Parameter 5 – Way of administration

The way of vaccine administration is subcutaneously.

3.1.4.3. Article 7(d)(iii) Medical treatments

Availability

Parameter 1 – Types of drugs available on the market

Types of drugs against BGC available on the market are antibiotics, for example, streptomycin or oxytetracycline.

Parameter 2 – Availability/production capacity (per year)

The availability and production capacity of drugs against BGC are unknown.

Effectiveness

Parameter 3 – Therapeutic effects on the field (effectiveness)

In bulls, antibiotic treatment can be successful if the bulls are less than 3 years old, while antibiotic treatment of older bulls is often not sufficient to clear the infection, and the older bulls remain life-long carriers of the bacterium (Blaser et al., 2008).

The effectiveness of antibiotic treatment in cows and heifers is unknown, since female cattle are mainly not treated, because treatment results are poor and most females develop protective immunity enabling them to resist re-infection (Taylor, 2002; Mshelia et al., 2007).

Feasibility

Parameter 4 – Way of administration

The way of administration of antibiotics against BGC is local in bulls.

3.1.4.4. Article 7(d)(iv) Biosecurity measures

Availability

Parameter 1 – Available biosecurity measures

Proper husbandry practices (e.g. careful selection of replacement cows and bulls) reduce the risk of introducing *C. fetus* into a herd. Only animals that are tested negative for *C. fetus* should be allowed to enter the herd. The risk of disease transmission can be substantially reduced or eliminated by applying sanitary protocols recommended by the International Embryo Transfer Society (IETS) and the OIE. The basic principle to ensure such a high level of biosecurity for semen relies on the concept of pathogen-free semen collection centres. In the case of embryos, practical guidelines have been published in the manual of IETS in order to provide risk management procedures ensuring the safety of herds using embryo transfer.

In the EU, Council Directive 88/407/EEC sets the measure for the animal health conditions of intra-Community trade and imports from third countries of frozen bovine semen. Among those testing of *C. fetus* infection should be carried out (either by IFAT or by culture) in the animals in approved semen collection centres.

Effectiveness

Parameter 2 – Effectiveness of biosecurity measures in preventing the pathogen introduction

The major biosecurity measure against BGC is the use of BGC-free semen or embryos and this will ensure that no BGC is introduced into a herd.

Feasibility

Parameter 3 – Feasibility of biosecurity measures

The diagnostic tests for BGC described in the OIE Manual to test if animals or materials are BGC-free are suitable to perform world-wide, even in LMIC.

3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products

Availability

Parameter 1 – Available movement restriction measures

According to Council Directive 88/407/EEC, if an animal of an AI station is tested positive for BGC, the AI station will be closed and production and trade or animals and their products are prohibited. The animals of the closed AI station are treated with antibiotics and must be tested negative for BGC for three times with 2 weeks interval, before the AI centre is allowed to continue the production and trade.

Effectiveness

Parameter 2 – Effectiveness of restriction of animal movement in preventing the between farm spread

The restriction of movement of BGC-infected animals to another farm will prevent the spread of BGC.

Feasibility

Parameter 3 – Feasibility of restriction of animal movement

If artificial insemination is used, the restriction of movement of animals from one farm to another is suitable for BGC.

3.1.4.6. Article 7(d)(vi) Killing of animals

Availability

Parameter 1 – Available methods for killing animals

For BGC, killing of animal measures are available.

Effectiveness

Parameter 2 – Effectiveness of killing animals (at farm level or within the farm) for reducing/stopping spread of the disease

If a BGC-infected animal is killed, the disease will not spread further from this animal.

Feasibility

Parameter 3 – Feasibility of killing animals

The economic loss by killing highly productive bulls can be very high. If the bull can be effectively treated with antibiotics, killing the infected bull is not necessary. If the antibiotic treatment is not effective and the bull remains BGC positive, it cannot be used for production in AI stations, and killing will be an option.

The economic loss of killing a cow will be much lower, but the feasibility of killing infected cows is questionable since recovery usually occurs spontaneously within 5 months and the acquired immunity protects the cows from re-infection.

Culling infected animals in a herd has proven to be effective to control the disease (Truyers et al., 2014).

3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products

Availability

Parameter 1 – Available disposal option

Semen or embryos contaminated with BGC can be destroyed.

Effectiveness

Parameter 2 – Effectiveness of disposal option

Disposal of the semen or embryos will prevent BGC spread.

Feasibility

Parameter 3 – Feasibility of disposal option

Disposal of BGC contaminated semen or embryos can be expensive, but is feasible world-wide.

3.1.5. Article 7(e) The impact of disease prevention and control measures

3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole

Parameter 1 – Cost of control (e.g. treatment/vaccine, biosecurity)

The cost to vaccinate a herd against BGC can vary significantly. Prices can be affected by number of cattle to be vaccinated, regional pricing and prices set by the vaccine supplier. A cost calculation is made in 2010 by the Government of Queensland (Queensland Government, online).

Parameter 2 – Cost of eradication (culling, compensation)

Within the EU, no compensation is given for the eradication of BGC-infected cattle or products thereof. The economic loss cost of the eradication is strongly dependent on the local situation.

Parameter 3 – Cost of surveillance and monitoring

Both preputial washings and vaginal mucus can be screened for the presence of *Campylobacter*. The total costs depend on the number of animals to be tested and are strongly dependent on the local situation. Bulls in AI centres are tested at least once per year, according to Council Directive 88/407/EEC.

Parameter 4 – Trade loss (bans, embargos, sanctions) by animal product

No data available about trade loss by animal product caused by BGC.

Parameter 5 – Importance of the disease for the affected sector (% loss or € lost compared to business amount of the sector)

In 2003, it was estimated that with approximately 20 million cows producing 11 million calves world-wide, a reduced weaning rate of 10% due to BGC results in the loss of 1.1 million calves yearly with a trade value of approximately 165 million $ (Campero et al., 2003).

3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures

The disease prevention and control measures, like testing the materials and treat the animals with antibiotics, are fully acceptable. Killing of animals to restrict spread meets societal problems.

3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals

Parameter 1 – Welfare impact of control measures on domestic animals

The control measures for BGC on domestic animals have no impact on their welfare.

Parameter 2 – Wildlife depopulation as control measure

Wild life depopulation is not required as control measure for BGC.

3.1.5.4. Article 7(e)(iv) The environment and biodiversity

Environment

Parameter 1 – Use and potential residuals of biocides or medical drugs in environmental compartments (soil, water, feed, manure)

The use and potential residuals of biocides or medical drugs in environmental compartments is hardly applicable for BGC.

Biodiversity

Parameter 2 – Mortality in wild species

BGC can possible cause embryonic death in feral cattle, but this disease is primarily a problem in domestic animals.

3.2. Assessment according to Article 5 criteria

This section presents the results of the expert judgement on the criteria of Article 5 of the AHL about BGC (Table 2). The expert judgement was based on Individual and Collective Behavioural Aggregation (ICBA) approach described in detail in the opinion on the methodology (EFSA AHAW Panel, 2017). Experts have been provided with information of the disease fact-sheet mapped into Article 5 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 5, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was 12. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 2: Outcome of the expert judgement on the Article 5 criteria for bovine genital campylobacteriosis

Criteria to be met by the disease: According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		**Final outcome**
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y

A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	Y
At least one criterion to be met by the disease: In addition to the criteria set out above at points A(i)–A(v), the disease needs to fulfil at least one of the following criteria		
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	Y
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	N
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	Y
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	N
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	N

Colour code: green = consensus (Yes/No).

3.2.1. Outcome of the assessment of bovine genital campylobacteriosis according to criteria of Article 5(3) of the AHL on its eligibility to be listed

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. According to the results shown in Table 2, BGC complies with all criteria of the first set and with two criteria of the second set; therefore, it is considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

3.3. Assessment according to Article 9 criteria

This section presents the results of the expert judgement on the criteria of Annex IV referring to categories as in Article 9 of the AHL about BGC (Tables 3–7). The expert judgement was based on ICBA approach described in detail in the opinion on the methodology. Experts have been provided with information of the disease fact-sheet mapped into Article 9 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 9, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was 12. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 3: Outcome of the expert judgement related to the criteria of section 1 of Annex IV (category A of Article 9) for bovine genital campylobacteriosis (CI: current impact; PI: potential impact)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
1	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present only in a very limited part of the territory of the Union	NC
2.1	The disease is highly transmissible	N
2.2	There are possibilities of airborne or waterborne or vector-borne spread	N
2.3	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	Y
2.4	The disease may result in high morbidity and significant mortality rates	N

At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
4(PI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	Y
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = non-consensus (NC).

Table 4: Outcome of the expert judgement related to the criteria of section 2 of Annex IV (category B of Article 9) for bovine genital campylobacteriosis (CI: current impact; PI: potential impact)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
1	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	NC
2.1	The disease is moderately to highly transmissible	Y
2.2	There are possibilities of airborne or waterborne or vector-borne spread	N
2.3	The disease affects single or multiple species	Y
2.4	The disease may result in high morbidity with in general low mortality	N
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
4(PI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	Y
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N

5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = non-consensus (NC).

Table 5: Outcome of the expert judgement related to the criteria of section 3 of Annex IV (category C of Article 9) for bovine genital campylobacteriosis (CI: current impact; PI: potential impact)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
1	The disease is present in the whole OR part of the Union territory with an endemic character	NC
2.1	The disease is moderately to highly transmissible	Y
2.2	The disease is transmitted mainly by direct or indirect transmission	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss	Y
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	NC
4(PI)	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	Y
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = non-consensus (NC).

Table 6: Outcome of the expert judgement related to the criteria of Section 4 of Annex IV (category D of Article 9) for bovine genital campylobacteriosis

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	Y
The disease fulfils criteria of sections 1, 2, 3 or 5 of Annex IV of AHL		Y

Colour code: green = consensus (Yes/No).

Table 7: Outcome of the expert judgement related to the criteria of section 5 of Annex IV (category E of Article 9) for bovine genital campylobacteriosis

Diseases in category E **need to fulfil criteria of Sections 1, 2 or 3 of Annex IV of AHL** and/or the following:		**Final outcome**
E	Surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently category E would apply)	Y

Colour code: green = consensus (Yes/No).

3.3.1. Non-consensus-questions

This section displays the assessment related to each criterion of Annex IV referring to the categories of Article 9 of the AHL where no consensus was achieved in form of tables (Tables 8 and 9). The proportion of Y, N or 'na' answers is reported, followed by the list of different supporting views for each answer.

Table 8: Outcome of the expert judgement related to criterion 1 of Article 9

Question		**Final outcome**	**Response**		
			Y (%)	**N (%)**	**Na (%)**
1 (cat. A)	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present only in a very limited part of the territory of the Union	NC	33	67	0
1 (cat. B)	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	NC	33	67	0
1 (cat. C)	The disease is present in the whole OR part of the Union territory with an endemic character	NC	42	58	0

NC: non-consensus; number of judges: 12.

Reasoning supporting the judgement

Supporting Yes for 1 (cat. A):

- The disease is mostly not present and only rare sporadic cases have been reported in a limited part of the Union (few MSs).
- There is no definition of a free status, neither at EU nor at OIE level.

Supporting Yes for 1 (cat. B):

- Only sporadic cases of the disease are reported in Scotland, Ireland, France, Spain, and the UK, but the microorganism is continuously present in the EU.
- The disease is sporadic in some countries with free-ranging extensive beef breeding systems using natural service.

Supporting Yes for 1 (cat. C):

- Cases of disease have been reported sporadically in several countries. However, the disease is asymptomatic and there are no testing measures currently in place and variable reporting can be an issue. Therefore, it is likely that the prevalence is underestimated and the disease may be more widespread across MSs, especially in those with free-ranging extensive beef breeding systems using natural service.
- It would appear to be endemic in a number of MSs, e.g. the UK, Ireland, France and Spain, where cases occur without any links to importation from elsewhere. The reporting of cases of BGC is sporadic rather than the presence of *C. fetus*.

Table 9: Outcome of the expert judgement related to criterion 4(CI) of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
4 (cat. C)	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	NC	25	75	0

NC: non-consensus; number of judges: 12.

Reasoning supporting the judgement

Supporting Yes:

- Losses are confined to beef breeding using natural service in extensive systems – i.e. no AI – the losses then occur in a particular type of production system in more than one MSs.

Supporting No:

- The infection causes low morbidity and no mortality due to control measures and the nature of the pathogen. So far, no significant losses in the EU have been reported.

3.3.2. Outcome of the assessment of criteria in Annex IV for bovine genital campylobacteriosis for the purpose of categorisation as in Article 9 of the AHL

As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E corresponding to point (a) to point (e) of Article 9(1) of the AHL) if it is eligible to be listed for Union intervention as laid down in Article 5(3) and fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d) as shown in Tables 3–7. According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. With respect to different type of impact where the assessment is divided into current and potential impact, a criterion will be considered fulfilled if at least one of the two outcomes is 'Y' and, in case of no 'Y', the assessment is inconclusive if at least one outcome is 'NC'.

A description of the outcome of the assessment of criteria in Annex IV for BGC for the purpose of categorisation as in Article 9 of the AHL is presented in Table 10.

Table 10: Outcome of the assessment of criteria in Annex IV for bovine genital campylobacteriosis for the purpose of categorisation as in Article 9 of the AHL

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	NC	N	N	Y	N	N	Y	N	N	N	N
B	NC	Y	N	Y	N	N	Y	N	N	N	N
C	NC	Y	Y	Y	Y	N	Y	N	N	N	N
D	Y										
E	Y										

According to the assessment here performed, BGC complies with the following criteria of the sections 1–5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a)–(e) of Article 9(1):

1) To be assigned to category A, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment BGC complies with criterion 2.3, but not with criteria 2.1, 2.2 and 2.4 and the assessment is inconclusive on compliance with criterion 1. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and BGC complies with criterion 4.
2) To be assigned to category B, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment BGC complies with criteria 2.1 and 2.3, but not with criteria 2.2 and 2.4 and the assessment is inconclusive on compliance with criterion 1. To be eligible for category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and BGC complies with criterion 4.
3) To be assigned to category C, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment BGC complies with criteria 2.1, 2.2, 2.3 and 2.4 and the assessment is inconclusive on compliance with criterion 1. To be eligible for category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a-d) and BGC complies with criterion 4.
4) To be assigned to category D, a disease needs to comply with criteria of Sections 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of Section 4, with which BGC complies.
5) To be assigned to category E, a disease needs to comply with criteria of Sections 1, 2 or 3 of Annex IV of the AHL and/or the surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, with which BGC complies.

3.4. Assessment of Article 8

This section presents the results of the assessment on the criteria of Article 8(3) of the AHL about BGC. The Article 8(3) criteria are about animal species to be listed, as it reads below:

'3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

a) they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely'.

For this reason, the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible and reservoir species or routes of transmission, which cover also possible role of biological or mechanical vectors.[3] According to the mapping, as presented in Table 5, Section 3.2 of the scientific opinion on the ad hoc methodology (EFSA AHAW Panel, 2017), the main animal species to be listed for BGC according to the criteria of Article 8(3) of the AHL are as displayed in Table 11.

Table 11: Main animal species to be listed for bovine genital campylobacteriosis according to criteria of Article 8 (source: data reported in Section 3.1.1.1)

	Class	Order	Family	Genus/species
Susceptible	Mammalia	Artiodactyla	Bovidae	Cattle (*Bos taurus*)
		Rodentia	Caviidae	Guinea pig (*Cavia porcellus*)
Reservoir	Mammalia	Artiodactyla	Bovidae	Cattle (*Bos taurus*)
Vectors	None			

4. Conclusions

TOR 1: *for each of those diseases an assessment, following the criteria laid down in Article 7 of the AHL, on its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;*

- According to the assessment here performed, BGC complies with all criteria of the first set and with two criteria of the second set, and therefore, can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

TOR 2a: *for each of the diseases which was found eligible to be listed for Union intervention, an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;*

- According to the assessment here performed, BGC meets the criteria as in Sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1) of the AHL. According to the assessment here performed, it is inconclusive whether BGC complies with the criteria as in Section 3 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (c) of Article 9(1) of the AHL. Compliance of BGC with the criteria as in Section 3 is dependent on a decision on criterion 1.

TOR 2b: *for each of the diseases which was found eligible to be listed for Union intervention, a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.*

- According to the assessment here performed, the animal species that can be considered to be listed for BGC according to Article 8(3) of the AHL is mainly cattle as susceptible and reservoir, as reported in Table 11 in Section 3.4 of the present document.

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[3] A vector is a living organism that transmits an infectious agent from an infected animal to a human or another animal. Vectors are frequently arthropods. Biological vectors may carry pathogens that can multiply within their bodies and be delivered to new hosts, usually by biting. In mechanical vectors the pathogens do not multiply within the vector, which usually remains infected for shorter time than in biological vectors.

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Abbreviations

AHAW	EFSA Panel on Animal Health and Welfare
AHL	Animal Health Law
AI	artificial insemination
BCG	Bovine genital campylobacteriosis
BVC	Bovine venereal campylobacteriosis
Cff	*Campylobacter fetus* subsp. *fetus*
CFU	colony forming unit
Cfv	*Campylobacter fetus* subsp. *venerealis*
ELISA	enzyme-linked immunosorbent assay
IETS	International Embryo Transfer Society
ICBA	Individual and Collective Behavioural Aggregation
IFAT	immunofluorescence antibody test
LMIC	low- and middle-income countries
OIE	World Organization for Animal Health
ToR	Terms of Reference

Appendix A – Presence/absence of BGC in EU

Table A.1: Presence/absence of BGC in domestic animals countries in Europe from 2005 to 2016, obtained from OIE WAHIS (OIE, online)

Country	Status for six month periods																							
	2005		2006		2007		2008		2009		2010		2011		2012		2013		2014		2015		2016	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Albania																								
Austria																								
Belarus																								
Belgium																								
Bosnia and Herzegovina																								
Bulgaria																								
Croatia																								
Cyprus																								
Czech Republic																								
Denmark																								
Estonia																								
Finland																								
Former Yugoslav Republic of Macedonia																								
France																								
Germany																								
Greece																								
Greenland																								
Hungary																								
Iceland																								

Country	Status for six month periods																							
	2005		2006		2007		2008		2009		2010		2011		2012		2013		2014		2015		2016	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Ireland																								
Italy																								
Latvia																								
Liechtenstein																								
Lithuania																								
Luxembourg																								
Malta																								
Moldova																								
Montenegro																								
Netherlands																								
Norway																								
Poland																								
Portugal																								
Romania																								
San Marino																								
Serbia and Monenegro																								
Slovakia																								
Slovenia																								
Spain																								
Sweden																								
Switzerland																								
United Kingdom																								

Key to colours

There is no information available on this disease.

Never reported.

Disease absent.

Disease suspected but not confirmed.

Infection/infestation.

Disease present.

Disease limited to one or more zones.

Infection/infestation limited to one or more zones.

Disease suspected but not confirmed and limited to one or more zones.

Annex A – Mapped fact-sheet used in the individual judgement on bovine genital campylobacteriosis

Annex A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2017.4990